UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC., *Plaintiff,* v. ACTAVIS LABORATORIES FL, INC., AND ACTAVIS PHARMA INC., *Defendants.*	C.A. No. 15-6934 (SRC-CLW) (consolidated) **ORAL ARGUMENT REQUESTED** **REDACTED VERSION**

ACTAVIS'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

Liza M. Walsh
Hector D. Ruiz
Eleonore Ofosu-Antwi
WALSH PIZZI O'REILLY FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 600
Newark, NJ 07102
Tel.: (973) 757-1100

Attorneys for Defendants Actavis Laboratories FL, Inc., and Actavis Pharma Inc.

Of Counsel:
J. Anthony Downs (admitted *pro hac vice*)
Brian T. Drummond (admitted *pro hac vice*)
Kenneth L. Mueller (admitted *pro hac vice*)
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
Tel.: (212) 570-1100

Daniel P. Margolis (admitted *pro hac vice*)
GOODWIN PROCTER LLP
The New York Times Building
620 8th Avenue
New York, NY 10018
Tel.: (212) 813-8800

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TABLE OF ABBREVIATIONS

Abbreviation	Description
Actavis's Products	The generic carbidopa/levodopa extended release capsules in four different dosage strengths, 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg/245 mg that are the subject of Actavis's ANDA No. 208522
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
Amiji Rpt.	Expert Report of Mansoor M. Amiji, Ph.D., R.Ph. Regarding Infringement of U.S. Patent Nos. 8,557,283, 9,089,608, and 9,463,246 dated May 19, 2017
ANDA	Abbreviated New Drug Application
Appel Decl.	Expert Declaration of Leah E. Appel, Ph.D. In Support of Actavis's Motion for Summary Judgment
AUC	area under curve
CD	carbidopa
C_{max}	maximum concentration
D.I. 56	Joint Claim Construction and Prehearing Statement
D.I. 59	Plaintiff Impax Laboratories, Inc.'s Opening Claim Construction Brief for the '474, '998, '283, '607, and '608 Patents

Abbreviation	Description
D.I. 93	Plaintiff Impax Laboratories, Inc.'s Revised Claim Construction Brief for U.S. Patent No. 8,377,474
D.I. 118	Opinion and Order Regarding Claim Construction
D.I. 123	Stipulation and Order Dismissing U.S. Patent Nos. 8,377,474; 8,454,998; and 9,089,607
ER	extended release
Ex. __	Exhibit to the Declaration of Brian Drummond In Support of Actavis's Reply Brief
FDA	Food and Drug Administration
IR	immediate release
Jenner Decl.	Expert Declaration of Peter G. Jenner, Ph.D. In Support of Actavis's Motion for Summary Judgment
LD	levodopa
Nangia	U.S. Patent Application No. 2007/0148238
Opening Br.	Actavis's Opening Brief in Support of Its Motion for Summary Judgment (D.I. 143)
Opp'n Br.	Impax's Brief in Opposition to Actavis's Motion for Summary Judgment (D.I. 158)
patents-in-suit	U.S. Patent Nos. 8,557,283; 9,089,608; 9,463,246; and 9,533,046
PK	pharmacokinetic

Abbreviation	Description
POSA	A person of ordinary skill in the art
PTO	United States Patent and Trademark Office
the ’283 patent	D.I. 143, Ex. 1, U.S. Patent No. 8,557,283
the ’608 patent	D.I. 143, Ex. 2, U.S. Patent No. 9,089,608
the ’246 patent	D.I. 143, Ex. 3, U.S. Patent No. 9,463,246
the ’046 patent	D.I. 143, Ex. 4, U.S. Patent No. 9,533,046
the ’474 patent	D.I. 143, Ex. 5, U.S. Patent No. 8,377,474
the ’427 patent	D.I. 143, Ex. 6, U.S. Patent No. 7,094,427 (no longer asserted)
the ’998 patent	U.S. Patent No. 8,454,998 (no longer asserted)
the ’607 patent	U.S. Patent No. 9,089,607 (no longer asserted)
Tr.	Deposition Transcript

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*Emphasis added unless otherwise noted.

Despite all of its rhetoric, Impax's opposition entirely fails to rebut the key issues for the Court to resolve in Actavis's motion for summary judgment. Summary judgment of noninfringement of all asserted claims remains warranted upon any reasonable application of the undisputed facts to the proper meaning of the claims.

I. ACTAVIS WILL NOT INFRINGE CLAIMS REQUIRING THAT THE CARBOXYLIC ACID IS IN A "DISTINCT BEAD"

All of the remaining asserted claims of the '283 and '608 patents require:

> [a] controlled release oral solid formulation of levodopa comprising:
>
> a. levodopa,
>
> b. a decarboxylase inhibitor, and
>
> c. a carboxylic acid that is not (a) or (b), wherein the carboxylic acid of (c) is in a distinct bead from (a) or (b).

[redacted] Impax argues (1) it did not disclaim coverage of formulations having carboxylic acid, LD and CD in the same bead; and (2) the claim language should be construed to permit both LD and CD to be in the same bead with carboxylic acid. On both issues, Impax is wrong.

A. Impax's Disclaimers of Formulations having LD/CD in the Same Bead with Carboxylic Acid Are Applicable to the '283 and '608 Patents

This Court has already analyzed the prosecution history of the '474 patent—to which both the '283 and '608 patents claim priority[1]—and concluded that "the applicants unmistakably disclaimed embodiments without a freely separable carboxylic acid component, ***regardless of the language used to amend the claims***." (D.I. 118 at 13-14 (footnote omitted).) Impax acknowledges that a disclaimer is applicable to claims in subsequent related patents if the

[1] The relationship among these three patents is straightforward. The '283 patent is a continuation of the '474 patent, and the '608 patent is a continuation of the '283 patent.

disclaimer was directed to the invention as a whole, rather than to particular language in the claims. (Opp'n Br. at 10.) [redacted]

Even if Impax's disclaimer were found to be directed only to the claim language of the '474 patent—which it is not—it would still be applicable to the claims of the '283 and '608 patents because of the substantial similarities between the claims. A disclaimer is applicable to claims of a later, related patent when the two patents "have the same or closely related claim limitation language." *Regents*, 717 F.3d at 943. Only "[i]f the language of the later limitation is significantly different, the disclaimer will not apply." *Id.*; *Invitrogen v. Clontech Labs.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005). The claims of the '474 patent require the carboxylic acid component "comprise[s] beads or granules" and be a "distinct component" from the immediate release component and controlled release components that contain CD and LD. (*E.g.*, D.I. 143, Ex. 5, '474 Patent, at claims 1 & 7.) Similarly, the claims of the '283 and '608 patents require that the carboxylic acid be in a "distinct bead" that does not include LD and CD. (D.I. 118 at 10.) Because these limitations are not "significantly different," the '474 disclaimer is applicable to the claims of the '283 and '608 patents.[2] *See, e.g.*, *Elkay Mfg. v. Ebcom Mfg.*, 192 F.3d 973 (Fed. Cir. 1999).

B. The Plain and Ordinary Meaning of The Claims Exclude Formulations having LD/CD in the Same Bead with Carboxylic Acid

Even if the Court finds that Impax did not disclaim coverage of formulations having LD

[2] This Court has recognized that a "component" may be a "bead" *or* a "granule." (D.I. 118 at 10.)

and CD in the same bead with carboxylic acid for purposes of the '283 and '608 patents, such formulations are nevertheless excluded by the plain meaning of the claim language. The language "wherein the carboxylic acid of (c) is in a distinct bead from [LD] or [CD]" itself means that the carboxylic acid is in a distinct bead that does not contain LD or CD, and this meaning is consistent with both the specification and file history. (Opening Br. at 10; *see also* Ex. 5, Appel Rebuttal Report at ¶¶ 28-36.) Nor does the term "distinct bead" have a broad meaning. Indeed, Impax has admitted that "distinct bead" is narrower than the "distinct component" term used in the '474 patent:

> The specification, therefore, makes clear that "distinct component" and "distinct bead" are not one and the same. Critically, in drafting the claims, the inventors chose to differentiate between the two, drafting claims directed to distinct components and separate claims directed to distinct beads ***when they meant that narrower embodiment***.

(D.I. 59 at 17.) The Court has also already reached this conclusion.[3] Thus, the '283 and '608 patent claims, reciting a "distinct bead," cannot be construed more broadly than the "distinct component" claims of the '474 patent, which the Court found exclude formulations with LD/CD in the carboxylic acid bead. *NTP v. Research in Motion*, 418 F.3d 1282, 1293 (Fed. Cir. 2005); *Microsoft v. Multi–Tech Sys.*, 357 F.3d 1340, 1349-50 (Fed. Cir. 2004).

The Court should also reject Impax's effort to rewrite the claims by arguing that "wherein the carboxylic acid of (c) is in a distinct bead from [LD] or [CD]" means only ***some*** of the CD/LD cannot be included in the carboxylic acid bead, and therefore ***some*** CD/LD can also be

[3] Impax's allegation that this Court's prior finding that "distinct bead" is narrower than "distinct component" was made with respect to a claim having different "contextual limitations" than the claims of the '283 and '608 patent is untenable. (Opp'n Br. at 10 n. 4.) The pre-amended claim with the "distinct bead" limitation discussed by the Court is identical to issued claim 1 of the '608 patent, with the irrelevant exception that the former referred to a "distinct particle bead" while the latter refers to a "distinct bead." (*Compare* Ex. 6, '474 Prosecution History, June, 11, 2012, Amendment at claim 1 *with* D.I. 143, Ex. 2,'608 patent at claim 1.)

included in the carboxylic acid bead. (Opp'n Br. at 13.) First, Impax arbitrarily divides the LD and CD of a formulation into two parts—that which is in the carboxylic acid bead and that which is not—and argues that only the LD and CD outside of the carboxylic acid bead count as the LD and CD referred to in the claim. Impax then contends that because the claims refer to a formulation "comprising" LD, CD, and a carboxylic acid, any LD or CD in the carboxylic acid bead is just additional ingredients that may be included in the formulation due to the open-ended nature of the word "comprising."

Such a reading should be rejected. It contradicts the claim language and rests on an incorrect application of the law regarding the term "comprising." The term "comprising" may permit the presence of additional unrecited components, but its application may ***not*** be extended so broadly as to alter or abrogate a claim limitation or avoid a relinquishment in claim coverage made during the prosecution. "'Comprising' is not a weasel word with which to abrogate claim limitations." *Spectrum Int'l v. Sterilite*, 164 F.3d 1372, 1380 (Fed. Cir. 1998). The Federal Circuit has rejected arguments, like Impax's, that contort the word "comprising" to allow for the addition of components that read out limitations of the claims. *See id.*; *Jeneric/Pentron v. Dillon*, 205 F.3d 1377, 1382 (Fed. Cir. 2000). For example, the claims at issue in *Jeneric* were directed to a two-phase composition comprising, *inter alia*, 0-1% cerium oxide, while the accused product contained 1.61% cerium oxide. 205 F.3d at 1382. The patent owner contended that the accused product nevertheless met the limitation because only 0.92% of the cerium oxide was part of the claimed two-phase composition, with the remaining 0.69% being part of a third phase, and therefore just an additional ingredient permitted by the "comprising" language. The Court rejected the patent owner's attempt "to carve out a portion of cerium oxide according to functions not recited in the claim" because "it would read out of claim 1 the express claim

ranges." *Id*. at 1382-83. Similarly here, the claims at issue do not limit the function (e.g., IR or CR) of the LD and CD from which the carboxylic acid bead must be distinct from, and Impax's attempt to do so should be rejected.

C. Actavis Will Not Infringe the "Distinct Bead" Claims under the Doctrine of Equivalents

[redacted] This Court has held that a POSA would understand the word "administering" to have an end point when the patient ingests the formulation. *Hoffmann-La Roche v. Apotex*, No. 07-4417, 2010 WL 1875569, at *7-10 (D.N.J. May 10, 2010) (J. Chesler); *Schering v. Glenmark Pharms.*, No. 07-1334, 2008 WL 4307189, at *8 (D.N.J. Sept. 16, 2008). The doctrine of equivalents does not allow Actavis to rewrite the claim language.

II. ADMINISTRATION OF ACTAVIS'S PRODUCTS WILL NOT INFRINGE CLAIMS REQUIRING A SPECIFIC PHARMACOKINETIC PROFILE

A. Actavis Did Not Waive Any of Its Defenses

With respect to the evidence showing that Actavis's Products do not meet the claimed PK limitations, Impax first alleges that Actavis waived its non-infringement argument related to the PK limitations by not properly disclosing those arguments in its contentions. This argument is

baseless. Local Rule 3.6(e) requires that Actavis provide written non-infringement contentions, including a claim chart identifying each claim and claim limitation at issue and "shall specifically identify for each claim which claim limitation(s) is/(are) literally absent . . . ." Actavis did just that, explaining why it will not meet each and every limitation at issue in this motion, in both its written explanation of non-infringement (Ex. 1, Actavis '246 Contentions at p. 5-6, 8-10; Ex. 2, Actavis '046 Contentions at p. 5-6, 8-10), and its claim charts (Ex. 1, Actavis '246 Contentions at Ex. 1, p. 1-14; Ex. 2, Actavis '046 Contentions at Ex. 1, p. 1-10).

In any event, the cases cited by Impax do not support its waiver argument. For example, the Court held in *Purdue* that because the defendant's non-infringement contentions completely failed to disclose that it intended to argue non-infringement for a particular claim, it could not "offer new evidence of non-infringement regarding the claim limitation 'appropriate patient population' but shall only rebut the sufficiency of Plaintiffs' evidence of infringement of this claim." *Purdue Pharm. Prods. v. Actavis Elizabeth*, No. 12-5311, 2015 WL 5032650, at *21 (D.N.J. Aug. 25, 2015). Not only did Actavis disclose that it intended to argue non-infringement for all of the asserted claims, but Actavis's motion for summary judgment of non-infringement is premised on the insufficiency of Impax's evidence of infringement. Therefore, even if Actavis had utterly failed to articulate its noninfringement position—which it did not—*Purdue* would permit Actavis to maintain its current arguments. Nor do any of the other cases cited by Impax come close to supporting a finding of waiver here.

Impax also alleges that Actavis has put forth new claim construction arguments in violation of the Local Rules. This is incorrect, and appears an attempt to distract the Court from Impax's own moving target approach to claim construction in this case. During claim construction, ***the parties agreed*** that the term "maximum concentration" would be given its plain

and ordinary meaning—the highest concentration in the PK profile. (D.I. 56 at 2; *see also* Opp'n Br. at 21 ("The parties agree that the plain and ordinary meaning of the term is the highest concentration of [LD] in the plasma concentration profile.").) Impax now alleges for the first time that, because the '246 and '046 patents were not yet involved in the case at that time, the parties' agreement as to the meaning of "maximum" is inapplicable to these patents. (Opp'n Br. at 18 n. 7.) But to the extent Impax believed that the agreed-upon construction of "maximum" was ***not*** applicable to similar claim language in the '246 and '046 patents, it was incumbent upon Impax, not Actavis, to disclose a different construction, which it never did. Actavis had no reason to believe that Impax would suddenly assert a new meaning for a term that appears in similar PK profile language for the earlier asserted patents.[4] *See NTP*, 418 F.3d at 1293.

The Court should also refuse to consider Impax's waiver arguments based on Impax's unreasonable delay in raising this issue. Impax has been in possession of Actavis's ANDA data ***for over two years***, Actavis's non-infringement contentions ***for nearly a year*** (*see* Ex. 1-2), Actavis's non-infringement expert reports ***for over four months*** (*see* D.I. 143, Jenner Decl. & Appel Decl.), and Actavis's motion for summary judgment ***for over two months*** (D.I. 143). Prior to filing its opposition brief, at no point did Impax inform Actavis that it believed Actavis's contentions lacked sufficient detail.

B. Impax's Analysis Regarding the PK Limitations Is Flawed

While Impax ostensibly agrees that the "maximum concentration," means "the highest concentration of levodopa in the plasma concentration profile," its purported "proof" of

[4] Impax's allegation that Actavis did not disclose a claim construction position for "40% fluctuation" is similarly baseless. In its motion for summary judgment, Actavis is simply asking the Court to apply the same meaning Impax ascribed to the term "40% fluctuation" during prosecution. To the extent Impax disputed this construction, the impetus was on Impax, not Actavis, to identify an alternative construction.

infringement reflects a complete disregard for this plain meaning. Instead, Impax applies a construction wherein the "maximum concentration" is not necessarily the peak corresponding to the highest concentration, but rather the first of two peaks if those peaks are "indistinguishable."[5]

Impax points to absolutely nothing in the intrinsic or extrinsic evidence supporting its new claim construction position. [redacted]

[5] Impax's use of the term, "indistinguishable" is a complete misnomer. [redacted]

[6] [redacted]

[redacted] Impax cannot ignore the full precision of the data and the literal scope of its claims. The data exists, and the claims say what they say. Consequently, Impax cannot establish that Actavis's Products will meet the PK limitations of the asserted claims.[7]

With regard to the "40% fluctuation" limitation, Impax's arguments are equally unavailing. Impax admits that, to overcome the prior art during prosecution of its patents, it calculated the 40% fluctuation range using both the 0.5 hour and 6 hour time points. (Opp'n Br. at 28.) While Impax makes numerous excuses for having done so, these litigation driven justifications were not communicated to the Examiner, nor do they appear in the intrinsic record. Nor does Impax dispute that if this interpretation of the "40% fluctuation" limitation is applied, administration of Actavis's Products would not infringe the asserted claims. A party cannot construe a claim one way during prosecution and another during litigation. *Spectrum Int'l*, 164 F.3d at 1379 ("[c]laims may not be construed one way in order to obtain their allowance and in a different way against accused infringers.") (quoting *Southwall Techs. v. Cardinal IG*, 54 F.3d 1570, 1581 (Fed. Cir. 1995)). Accordingly, summary judgment of noninfringement is appropriate.[8]

[7] [redacted]

[8] [redacted]

III. ACTAVIS WILL NOT INDUCE OR CONTRIBUTE TO INFRINGEMENT OF ANY OF THE ASSERTED CLAIMS OF THE ’246 OR ’046 PATENTS

Even if the Court agrees that there is a genuine issue of material fact to resolve related to Impax’s argument that administration of Actavis’s Products will meet the limitations of the asserted claims of the ’246 and ’046 patents, nothing in Impax’s opposition cures its lack of proof that Actavis induces or contributes to infringement. Impax does not dispute, for example, that patients administered Actavis’s Products under fed conditions will not meet the PK limitations of these claims.

Instead, Impax’s opposition is premised solely on another new, unsupported claim construction. The asserted claims of the ’246 and ’046 patents require “orally administering to ***a human patient in need of such treatment*** a multiparticulate formulation … wherein following a single dose administration of the multiparticulate formulation ***the patient’s*** levodopa plasma profile comprises . . . .” [redacted]

[redacted]

9 [redacted]

[redacted]

In support of its new position[10], Actavis relies on *Braintree Labs. v. Novel Labs.*, where the Federal Circuit construed "a patient" to mean "the general class of persons to whom the patented compositions are directed, i.e., a patient population." 749 F.3d 1349, 1357 (Fed. Cir. 2014). But the claim at issue in *Braintree* was not even directed to a method of treatment—as are the patents here—but rather to a composition. *Id.* at 1353. This is a critical distinction. Whereas the claims at issue here state "wherein … ***the patient's*** levodopa plasma concentration profile comprises," the claims at issue in *Braintree* stated "wherein ***the composition*** does not produce any clinically significant electrolyte shifts and does not include phosphate." *Id.* The Court's construction in *Braintree* was necessitated to avoid the "absurd" result that one patient in a population having the claimed properties would render the composition itself infringing, even if the composition did not result in the claimed properties in most patients. *Id.* at 1357.

As subsequent Courts have recognized, *Braintree* did not "affect a massive change in the law of claim construction" such that "patient" should always be construed to refer to a population rather than in the context of a particular patent. *Recro Tech. v. Actavis Labs. FL*, No. 14-1118, 2015 WL 9590585, at *1 n.1 (D. Del. Dec. 29, 2015). "Patient" must be construed under the same guidelines as any other claim term. Notably, Impax points to nothing in the patent claims, specification, prosecution history, or extrinsic evidence supporting this new construction. In fact, Impax's own expert, Dr. Amiji, disagrees with its interpretation. [redacted]

[redacted]

[10] Ironically, Impax accuses Actavis of failing to previously disclose its position that "the patient" means "the patient," when this is the first time that Impax has suggested anything to the contrary. (Opp'n Br. at 29.)

[redacted]

[redacted] The Court should refuse to adopt Impax's baseless proposed construction for this term, and therefore find that Actavis will not induce infringement of the asserted claims of the '246 or '046 patent.[11]

IV. CONCLUSION

For the foregoing reasons, Actavis respectfully request its motion be granted.

Dated: January 15, 2018

WALSH PIZZI O'REILLY FALANGA LLP
Attorneys for Defendants Actavis Laboratories FL, Inc. and Actavis Pharma, Inc.

s/ Liza M. Walsh

Liza M. Walsh
Hector D. Ruiz
Eleonore Ofosu-Antwi
WALSH PIZZI O'REILLY FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd.,Suite 600
Newark, NJ 07102
(973) 757-1100

OF COUNSEL (admitted *pro hac vice*):
J. Anthony Downs
Brian T. Drummond
Kenneth L. Mueller
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, Massachusetts 02210
(617) 570-1929

Daniel P. Margolis
GOODWIN PROCTER LLP
620 Eight Avenue
New York, NY 10018
(212) 813-8800

[11] Impax likewise relies solely upon this new construction to support its allegation of contributory infringement. (Opp'n Br. at 30.) Accordingly, the Court should find that Actavis will not contribute to infringement of the asserted claims of the '246 or '046 patent for substantially similar reasons.